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Medical Imaging Applications

DEC 16 2004

510(k) SUMMARY

Submission in accordance with the requirements of 21 CFR Part 807.87(h)

1) Submitter	Medical Imaging Applications LLC 832 Forest Hill Dr. Coralville IA 52241 phone: (319) 358-1529 fax: (319) 688-5296 e-mail: mia-llc@mia-llc.com
Contact person	Milan Sonka
Prepared	October 10, 2004
2) Device Name:	"Vascular Tools 5" consisting of modules: "Brachial Analyzer 5", "Carotid Analyzer 5"
Common name	Picture Archival and Communications System
Classification name:	Picture Archival and Communications System, Class II
Regulation Number:	892.2050
3) Predicate Device:	QLAB - Philips Ultrasound, Inc.

4) Description of the device:

"Vascular Tools 5" quantification software system is a state-of-the-art product for computer-aided assessment of vascular diameter, intima-media thickness derived from existing ultrasound images. Based on computer-aided detection of vessel wall borders within a region of interest of a single longitudinal ultrasound image or a sequence of longitudinal ultrasound images, vascular diameter and/or IMT are reported for each ultrasound image frame or a user-defined subset of image frames.

"Vascular Tools 5" is a proprietary software program for vascular ultrasound image quantification designed for installation on an IBM-PC-compatible personal computer and use with Windows 2000 or XP operating platform. It provides tools for display, selection, evaluation, and storage of multiple loops of vascular ultrasound image data. Furthermore, "Vascular Tools 5" facilitate import and export of complete studies in "Vascular Tools 5" format, and the export of results into general spreadsheets, databases, or in ASCII formats for further statistical analysis of study results by the users.

5) Intended use:

"Vascular Tools 5" have been developed for the objective and reproducible analysis of vascular ultrasound images. The "Vascular Tools 5" data analysis program package components are intended to:

- Brachial Analyzer: Determine brachial artery diameter
- Carotid Analyzer: Determine carotid artery diameter
- Carotid Analyzer: Determine carotid artery intima-media thickness

In each of the above listed intended use items, the Vascular Tools software aids the human expert to obtain quantitative information about the vascular morphology. Same as when using standard clinical

methods, the human expert analyst is responsible for inspection and - if needed - editing of the identified vessel wall borders prior to their approval.

6) Substantial equivalence Information:

The "Vascular Tools 5" software is believed substantially equivalent to the predicate devices of Philips Medical Systems' K040227"QLAB QUANTIFICATION SOFTWARE" by using the same technological characteristics and identical intended use.

Technological differences between the subject and predicate devices are minor and presented above. It is concluded that the differences in technical characteristics between the two products are not significant in that there are no features in the subject device that raise new questions regarding safety nor that could result in a decrease of effectiveness as compared to the predicate device.

7) Conclusions respecting safety and performance - Level of Concern:

It is the opinion of *Medical Imaging Applications LLC* that "Vascular Tools 5" is a safe image quantification software and potential hazards are controlled by a risk management plan for the software development process (see Appendix B), including hazard analysis (see Appendix C), verification and validation tests (see Appendix D). In Medical Imaging Applications LLC's opinion, the level of concern for the stand-alone software to view images is moderate. The use of "Vascular Tools 5" quantification software neither changes the intended use of ultrasound scanners in practice, nor does the use of software result in any new potential hazards.

8) Validation and test conclusions

Test and validation results support the conclusion that the actual device performance satisfies the design intent. Actual device performance as tested internally conforms to the system performance specifications. Detailed assessment of "Vascular Tools 5" performance is given in Appendix D.

9) Release version number

The software release described in this document has a release version number: Version 5.1.1, release date June 1, 2004

10) Revision Level History
No revisions were recorded to date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2004

Medical Imaging Applications, LLC
c/o Mr. Milan Sonka
832 Forest Hill Dr.
Coralville, IA 52241

Re: K033266
Trade Name: Vascular Tools 5
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable diagnostic computer
Regulatory Class: II (two)
Product Code: DQK
Dated: October 10, 2004
Received: October 13, 2004

Dear Mr. Sonka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K033266**

Device Name: "Vascular Tools 5" consisting of modules: "Brachial Analyzer 5", "Carotid Analyzer 5"

Indications For Use: "Vascular Tools 5" software program has been developed to aid in quantitative analysis of longitudinal vascular ultrasound images, particularly to determine vascular diameter and intima-media thickness, as well as their changes as depicted in brachial and carotid arterial ultrasound images.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K033266